Supporting Statement for Retiree Drug Subsidy (RDS) Application and Instructions OMB # 0938-0957 CMS-10156

A. Background

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR Subpart R plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to the Centers for Medicare & Medicaid Services (CMS) with a list of retirees for whom it intends to collect the subsidy. Once CMS reviews and analyzes the information on the application and the retiree list, notification will be sent to the plan sponsor about its eligibility to participate in the Retiree Drug Subsidy (RDS) Program.

B. Justification

1. Need and Legal Basis

Under §1860D-22 of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR Subpart R plan sponsors (employers or unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. Plan sponsors must submit a complete application to CMS in order to be considered for the RDS program.

2. Information Users

CMS has contracted with an outside vendor (ViPS) to assist in the administration of the RDS program; this effort is called the RDS Center. Plan Sponsors will apply on-line for the retiree drug subsidy by logging on to the RDS secure web site. Once the plan sponsor submits the RDS application via the RDS website the staff at the RDS Center will analyze the application to determine whether the plan sponsor qualifies for the retiree drug subsidy.

3. Use of Information Technology

The RDS program is an entirely new benefit and will not go into effect until January 1, 2006. The data collected on the application are not currently being collected through any other mechanism.

The application process for the RDS will be a completely electronic process (100%). The only instance when hard copy/paper applications can be submitted is when the RDS Center is experiencing technical difficulties. The completion and submission of the RDS application (including the Plan Sponsor's Authorized Representative's electronic signature) will take place on-line via the secure RDS Center web site located at http:\\rds.cms.hhs.gov.

4. <u>Duplication of Efforts</u>

The RDS program is an entirely new benefit and will not go into effect until January 1, 2006. The data collected on the application are not currently being collected through any other mechanism. Therefore, this information collection does not duplicate any other effort and the information cannot be obtained from any other source.

Consideration has been given to the duplication of the submission of the Plan Sponsor retiree list. In an effort to avoid duplication, plan sponsors who have an existing Voluntary Data Sharing Agreement (VDSA) can submit their retiree list via the Coordination of Benefits (COB) contractor to the RDS Center. Plan Sponsors who do not currently have a VDSA with CMS are being encouraged to enter into one.

5. Small Businesses

CMS has made efforts to minimize the burden that this collection of information will have on all submitting entities including small businesses. Towards this end, CMS has made the entire application process completely electronic. The completion and submission of the RDS application (including the Plan Sponsor's Authorized Representative's electronic signature) will take place on-line via the secure RDS Center web site located at http:\\rds.cms.hhs.gov. In addition, CMS is encouraging plan sponsors to utilize existing VDSAs, or enter into new VDSAs for the submission of the plan sponsor retiree list. The benefits of receiving the subsidy payments will far exceed the cost associated with applying for the subsidy.

6. Less Frequent Collection

42 CFR Subpart R of the final rule stipulates the required timelines for the submission of the RDS application and retiree list. For plan years that end in 2006, and application and retiree list must be submitted to the RDS Center by September 30, 2005. For years thereafter and application for the given plan year must be submitted no later than 90 days prior to the beginning of the plan year. Throughout the plan year sponsors must submit (in addition to the list submitted at the annual application) updated retiree lists. The plan sponsor can elect to make this submission monthly, or quarterly via the VDSA process.

Deviation from those requirements would result in noncompliance.

7. Special Circumstances

42 CFR Subpart R requires plan sponsors to submit an application for the RDS on an annual basis.

- Plan Sponsors approved to receive the RDS payments will be required to submit updates to submitted retiree information on a monthly basis. If a Plan Sponsor enters into a Voluntary Data Sharing Agreement (VDSA) with the Medicare Coordination of Benefits (COB) contractor then the aforementioned reporting requirement is reduced to quarterly.
- There are no special circumstances where plan sponsors would be required to prepare a written response to a collection of information in fewer than 30 days after receipt of it.
- There are no special circumstances where plan sponsors would be required to submit more than an

- original and two copies of any document.
- There are no special circumstances that would cause an information collection in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study.
- There are no special circumstances that would cause an information collection requiring the use of a statistical data classification that has not been reviewed and approved by OMB.
- There are no special circumstance that includes a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.
- There are no special circumstances where plan sponsors would be required to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.
- There <u>are</u> special circumstances that would cause an information collection to be conducted which would require plan sponsors to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years. 42 CFR 423.888(d)(1) through (3) requires that plan sponsors maintain the following records for 6 years after the expiration of the plan year in which costs were incurred:
 - 1. Reports and working documents of the actuaries who wrote the attestation submitted in accordance with 42 CFR 423.884(a).
 - 2. All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment including the underlying claims data.
 - 3. Any other records specified in additional CMS guidance.

8. Federal Register/Outside Consultation

We are requesting a 60-day Federal Register comment period. A 60-day Federal Register notice was published on 9/9/05, attached.

We have consulted on an ongoing basis with business groups, industry groups, union groups, health benefit administrators, and private actuaries to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, reporting format, and on the data elements to be recorded, disclosed, or reported. In addition, the RDS Center will be conducting industry focus groups with the aforementioned groups to continue to improve the operations of the RDS Program.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We have assured potential applicants to the RDS Program that laws, regulations, and guidance associated with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and the Privacy Act of 1974 (as amended) will apply to any information collected by CMS for purposes of this program.

The regulations governing the RDS Program (42 CFR 423.888(c)) require that officers, employees,

and contractors of the U.S. Department of Health & Human Services (DHHS) may use information collected for the RDS Program only for the purposes of, and to the extent necessary, to carry out the requirements of the program. We have assured on an ongoing basis that any proprietary information submitted by applicants will not be disclosed.

11. Sensitive Questions

No questions of a sensitive nature, such as sexual behavior and attitudes, and religious beliefs are asked. The data collected is to determine whether an individual is Medicare-eligible, and not already enrolled in a Part D plan.

12. <u>Burden Estimates (Hours & Wages)</u>

Based on the impact analysis done for the final rule, for each entity we estimate an average of 2 hours administrative work to assemble the applications, 31 hours for systems changes to extract identifying information on qualifying covered retirees, about 7 hours for preparation of the actuarial attestations, and about 30 minutes to sign the required sponsor agreement. This is a total of approximately 40.5 hours for each prescription drug plan. Based on the impact analysis the estimate for the number of entities applying for the subsidy is 50,000 in 2005. This number includes public, private and union sponsors. The total number of hours for all entities applying for the subsidy is 2,025,000 (40.5 x 50,000).

13. Capital Costs

We have determined that there are no new capital outlays required to participate in the RDS Program. We have assumed that all businesses will own at least one computer and have access to the internet.

14. Cost to Federal Government

For fiscal year 2006 the cost to the Federal Government is estimated to be \$13,827,437. This amount includes the \$13,427,437 that is being paid to the contractor who won the award to administer the RDS Program. In addition, there are five CMS full time employees (FTEs) dedicated to the RDS Program with an estimated cost to the Federal Government of \$400,000 per year. This number is derived multiplying the average employee hourly salary x the number of FTEs assigned to the Program x 40 hours a week x 52 weeks a year.

15. Program/Burden Changes

There are no program/burden changes.

16. Publication/Tabulation Dates

The collection of information both on the RDS application and the retiree list will not be published.

For calendar year 2006, plan sponsors must submit applications between August 1, 2005 and September 30, 2005. Every year thereafter, they will submit and application 90 days before the start a new plan year. In addition to the annual application Plan Sponsors must submit a retiree list to the RDS Center. Plan Sponsors can elect to submit this list on a monthly basis, or on a quarterly basis

using the VDSA process.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

C. Collections of Information Employing Statistical Methods

Not applicable. The information collection does not employ statistical methods.